IN THE UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

PAUL QUAST and JULIE SPRAFKA, Plaintiff, v. DEPUY ORTHOPAEDICS, INC., an Indiana Corporation, and MEDICAL DEVICE BUSINESS SERVICES, INC., an Indiana Corporation, Defendants.	Cause No. 0:22-cv-00331 (DWF/TNL) **PLAINTIFF'S EXPERT DISCLOSURE PURSUANT TO F.R.C.P. 26(a)(2)**

Julie Sprafka (hereinafter "Plaintiff" or "Mrs. Sprafka"), by and through her attorney Stephen J. Baity of BAITY & LINDVIG, LLC, hereby submits the following expert disclosures pursuant to Fed.R.Civ.P.26(a)(2), disclosing the individuals who may be called to testify at trial:

1. Mari S. Truman, M.S., P.E.
   OrthoBioMech, LLC
   221 N. Union St.
   Warsaw, IN 46580
   Phone: (574) 265-1726

Ms. Truman is a retained expert. A copy of the report setting forth Ms. Truman's documentation, information considered, opinions, and the bases and reasons for those opinions is attached at **Exhibit 1.** Also attached is Ms. Truman's curriculum vitae, which contains her education, background, professional credentialing, and list of publications. Finally, Ms. Truman's testimony history is also attached. **Exhibit 2.** Any of the documents, data, or other materials used by Ms. Truman in preparing her report or bases of her opinions may be used as exhibits at trial. Plaintiff anticipates supplementing the disclosure of her opinions following her deposition.

Ms. Truman will testify the Attune knee system is defective and unreasonably dangerous. The cement interface surface of the tibial implant baseplate in the Attune knee system is defective in design. The specific defects in the design are discussed in detail in her report. The design of the tibial implant baseplate caused the implant to fail. The defect in the design of the Attune knee system caused Mrs. Sprafka pain and required the total knee replacement.

Ms. Truman will testify there are numerous alternative knee system designs including knee systems designed and marketed by DePuy that would meet the same need, are safe and do not present the same risks of failure. As discussed in detail in her report, DePuy could have eliminated the unsafe character of the Attune knee system without impairing the usefulness of the system. The alternate designs that would eliminate the defect would not have been expensive or substantially impact the manufacturing of the knee system.

The Attune knee System failed through no fault of Mrs. Sprafka. Mrs. Sprafka could not have avoided the danger presented by the defective design by the exercise of care in the use of the knee system. A patient who has an Attune knee implant would not know or have reason to know about the danger of the failure of the knee system caused by the defective design.

2. **Andrea M. Saterbak, M.D.**
   Twin Cities Orthopedics
   5715 Memorial Avenue, N., Suite 200
   Stillwater, MN 55082

Dr. Saterbak is a non-retained expert. She is a board-certified orthopedic surgeon with a sports medicine subspecialty certification. She specializes in knee and shoulder conditions with an interest in joint replacement of both the knee and shoulder. Dr. Saterbak completed her residency at the University of Iowa Department of Orthopedic Surgery between 1993-1997, and her Orthopedic Sports Medicine Fellowship at the Steadman-Hawkins Clinic in Vail, Colorado

1997-1998. She received her medical degree from Creighton University School of Medicine in 1992. Dr. Saterbak is licensed to practice medicine in the State of Minnesota. She has traveled as a consulting physician with the US Ski Team on the World Cup Tour since 1998.

Dr. Saterbak will testify Julie Sprafka came to see her with complaints of pain and swelling in her right knee. She examined Mrs. Sprafka and requested diagnostic imaging of the right knee. She diagnosed Mrs. Sprafka with osteoarthritis without evidence of trauma or infection. She also determined Plaintiff was a proper candidate for a total knee arthroplasty and she recommended implanting the Attune Knee System.

Dr. Saterbak will testify she selected the Attune knee system, in part, based on representations made by DePuy. DePuy represented the Attune knee system was state of the art and that it would perform as expected without complications. The sales materials and training materials represented the Attune knee system would be stable and allow patients to return to an active lifestyle. She will also testify the information provided to her by DePuy prior to the 2016 surgery did not identify the risk of cement de-bonding from the tibial baseplate.

When she reviewed the risks of the surgery with Mrs. Sprafka before the 2016 surgery, she did not warn her the tibial baseplate would de-bond or that the cement would not safely secure the tibial implant baseplate. When she implanted the tibial baseplate, she did not appreciate the risk that the cement would not adhere to the device even when she used the proper surgical technique to implant the device.

Dr. Saterbak implanted the Attune Knee System in Julie Sprafka's right knee on August 18, 2016, at the Lakeview Hospital, Stillwater, Minnesota. She implanted the Attune Tibial Base

Bearing size 6, REF # 1506-00-005 into Mrs. Sprafka's right knee. She also used DePuy CMW 2 Bone Cement, REF #3322-020, Lot #8280491.

Dr. Saterbak will testify she received training from DePuy on the proper procedure for implanting the Attune Total Knee System. She will testify when she implanted the Attune knee device into Julie Sprafka she followed DePuy's training, instruction and per the surgical technique provided by DePuy to orthopedic surgeons. She will testify she properly prepared the cement, and she properly implanted the tibial baseplate into Ms. Sprafka's tibia. Dr. Saterbak will testify there was nothing in her surgical procedure that would have caused or contributed to the subsequent aseptic loosening to the Attune Knee System or the revision surgery.

Dr. Saterbak is expected to testify she did not know, at the time of the surgery, about the revisions DePuy was making to the tibial baseplate including deeper recessed pockets on the underside of the tibial baseplate, the extension of the keel, or the change in the surface of the tibial baseplate. She also expected to testify at the time of Mrs. Sprafka's surgery she did not know DePuy intended to request the Federal Drug Administration to approve the changes in the design of the tibial baseplate under a 510(k) protocol or that a new improved version of the Attune Total Knee System would be introduced into the marketplace.

Dr. Saterbak is expected to testify the Attune Total Knee System she implanted into Julie Sprafka's knee came in a sterile package. She did not alter or change the tibial baseplate before or during implantation. She implanted the Attune knee system including the tibial baseplate without substantial change in the condition in which it was manufactured and sold.

Dr. Saterbak is expected to have information and knowledge regarding Plaintiff's pre and post-surgery status. She will testify regarding her examination of Plaintiff's right knee before and

after the surgery as documented in her medical records including post-surgery visits during which Mrs. Sprafka complained of pain in the right knee. She may have knowledge as to the necessity and reasonableness of the charges incurred for the medical care and treatment provided to the Plaintiff or that was provided at her direction and/or under her supervision.

Dr. Saterbak may testify as a treating physician in this case with regard to her care and treatment of the Plaintiff for the procedures she performed on Plaintiff's right knee. Dr. Saterbak will testify regarding her medical records, including the records from Lakeview Hospital, Twin City Orthopedics and Health Partners Clinics medical records, which were obtained and disclosed by Defendants. Dr. Saterbak will testify consistent with and in detail about all opinions and matters addressed in those medical records, reports, notes, charts, bills and related material. This includes her review of the radiology films, and she is endorsed to show these films to the jury and explain them. Dr. Saterbak is endorsed to testify regarding her review and study of the treatment, care and medical records that Mrs. Sprafka underwent including the medical examination, history, evaluation, surgeries, review of records, diagnosis, prognoses, and treatment of Plaintiff related to her total knee arthroplasty and subsequent revision surgery. She is endorsed to testify that these treatments and the bills were reasonable and necessary.

Dr. Saterbak's deposition is scheduled for March 27, 2023. This endorsement will be supplemented and modified after her deposition. It is anticipated she will provide additional opinions and amplify the opinions contained in this disclosure.

3. **Kristoffer Breien, M.D.**
Summit Orthopedics
2620 Eagan Woods Drive
Eagan, MN 55121

Dr. Breien is a non-retained expert witness. Dr. Breien is licensed to practice medicine in the State of Minnesota He received his medical degree from Creighton University School of Medicine in 1994 and he performed his residency in orthopedics from Creighton-Nebraska University Health Foundation. He is the Orthopedic Surgeon who performed the right total knee arthroplasty in 2016 for Plaintiff. He is expected to have information and knowledge regarding Plaintiff's pre and post-surgery status and the Attune knee system. He may have knowledge as to the necessity and reasonableness of the charges incurred for the medical care and treatment provided to the Plaintiff or that was provided at his direction and/or under his supervision.

Dr. Breien will testify as a treating physician in this case with regard to his care and treatment of the Plaintiff for the procedures he performed on Plaintiff's right knee. Dr. Breien will testify regarding his medical records, including records from Summit Orthopedics, Woodlake Medical Center as well as the surgical records and the 3-phase radionuclide bone scan of Plaintiff' right knee. Defendant independently gathered these medical records and disclosed them in this case. Dr. Breien will testify consistent with and in detail about all opinions and matters addressed in those medical records, reports, notes, charts, bills and related material. This includes his review of the radiology films, and he is endorsed to show these films to the jury and explain them.

Dr. Breien is also endorsed to testify regarding his review and study of the treatment, care and medical records that Mrs. Sprafka underwent including the medical examination, history,

evaluation, surgeries, review of records, diagnosis, prognoses, and treatment of Plaintiff related to her total knee arthroplasty.

Dr. Breien is expected to testify that all medical treatment and care that he provided to Plaintiff, and the costs thereof, were reasonable, necessary, and caused by the failure of the Attune knee System. All of Dr. Breien's opinions are expressed to a reasonable degree of medical probability.

In June 2020, Julie Sprafka reported to Dr. Breien that since the implant surgery in 2016 she has had pain in her right knee and that it felt like the it never quite took. The knee was particularly painful with activity and weightbearing. The x-rays showed a "little lucency between the cement mantle and the anterior portion of the tibial stem." The bone scan showed "moderate increased tracer uptake is also demonstrated about all components of the right knee arthroplasty hardware." The scan showed changes of "osteolysis/hardware loosening". The x-rays and bone scans indicated the tibial implant was de-bonded.

Dr. Breien diagnosed Plaintiff with a failed arthroplasty in the right knee caused by loosening of the implant at the tibial base. He determined there was no evidence of infection or trauma to the knee. He recommended a revision surgery to replace the Attune total knee system.

On September 15, 2020, Dr. Breien performed the revision surgery due to the failure of the Attune knee system. When he performed the revision surgery, he observed the tibial implant baseplate had de-bonded and came free from the tibia with minimal effort. He stated: "I then brought the tibia forward and tapped it with the drift from below. The tibial implant separated from the cement mantle which remained intact with just 1 tap. This confirmed our suspicion." He also observed there was little or no cement adhered to the tibial baseplate. He found that when the

tibial baseplate was removed from the tibia it left a clear impression in the cement mantle consistent with his previous revision surgeries where the Attune tibial baseplate had debonded. Dr. Breien will testify he has had other patients whose Attune knee implant failed in a manner similarly to Mrs. Sprafka. His observation during Julie Sprafka's revision surgery was the method of failure was similar to his other revision surgeries where the Attune tibial base had debonded and caused the knee device to become loose.

Dr. Breien will testify the Attune knee system did not perform as represented by DePuy. It was not stable and it prevented patients including Mrs. Sprafka from having an active lifestyle.

Dr. Breien will testify the failure of the cement to bond to the tibial base caused aseptic or mechanical loosening in the Attune Knee System which resulted in the need to perform the revision surgery. Dr. Breien will testify the debonding of the Attune tibial base was the sole cause of Mrs. Sprafka's revision surgery. He will testify but for the failure of the Attune knee system Mrs. Sprafka would not have required the knee revision surgery.

It is also expected Dr. Breien will testify his observations from the revision surgery are consistent with the reported findings from other surgeons that have performed revision surgeries to replace the Attune Total Knee System.

Dr. Breien will testify there was no evidence of infection or trauma that would explain the debonding. In his opinion, the tibial baseplate should not have de-bonded in the manner he observed. In is expected Dr. Brien will testify the Attune knee system implanted in Julie Sprafka in 2016 was defective. He does not believe Mrs. Sprafka acted improperly in a manner that caused the failure of Attune knee system. But for the debonding of the tibial baseplate, Mrs. Sprafka would not have needed the 2020 revision surgery.

4. **Elizabeth M. Senoraske, M.P.T., Physical Therapist**
   River Valley Physical Therapy
   215 S. 2nd St., Suite 10,
   River Falls, WI, 54022-403
   Phone: (715) 426-7852

Ms. Senoraske is a physical therapist and she treated Plaintiff after her total knee arthroplasty in 2016 and after her revision surgery in 2020. Defendants independently obtained the River Valley Physical Therapy. She will testify consistent with and in detail about all opinions and matters addressed in those medical records, reports, notes, charts, bills, and related material. Ms. Senoraske is endorsed to testify regarding her review and study of the treatment, care and medical records that Mrs. Sprafka underwent including the medical examination, history, evaluation, surgeries, review of records, diagnosis, prognoses, and treatment of Plaintiff related to her total knee arthroplasty and subsequent revision surgery. She is endorsed to testify that the physical therapy treatments and the bills were reasonable and necessary.

Ms. Senoraske will testify Julie Sprafka faithfully attended and provided excellent effort during the physical therapy sessions. From her observations, the Attune knee system did not perform as expected. Mrs. Sprafka did everything asked of her to rehabilitate the knee. Despite her best efforts, Mrs. Sprafka had limitations in the range of motion and expressed pain. By contrast, the knee system implanted in 2020 substantially performed better than the Attune knee system. Mrs. Sprafka's recovery was faster with less pain after the 2020 revision than she did after the 2016 implant and without complications.

Respectfully submitted,

/s/*Stephen J. Baity*

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CERTIFICATE OF SERVICE

I hereby certify that on the 10th day of March 2023, I electronically filed a true and correct copy of the foregoing document with the Clerk of the Court using CM/ECF, and that the foregoing document has been served upon the following counsel of record via transmission of Notices of Electronic Filing generated by CM/ECF:

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